# RESEARCH PROTECTIONS UPDATE

*News and Comment on the Protection of Human Subjects and Animals in Navy Research*

***Volume 1, Number 7*** ***humanresearch@us.med.navy.mil*** ***October 2006***

***Comment***

## DON HRPP Web-Based Training Comes On Line

Training for human research protections for senior Navy leaders, researchers, Institutional Review Board members, and others working in DON research will take a huge step forward with the launch of a constellation of Navy web-based education and training modules.

The DON HRPP uses a series of concise yet comprehensive modules developed by the non-profit Collaborative Institutional Training Initiative (CITI) as the training foundation for all Navy personnel engaged in research with human subjects. Accessible through the CITI website, the modules offer the full spectrum of human research protections training required by the new DON HRPP Education Policy (page 2).

The new training package, with launch planned for early November, has been designed to be eminently "user-friendly." Navy personnel seeking the most authoritative training available simply go to the CITI website (www.citiprogram.org), log on, and follow directions to access the Department of the Navy training site. They then will select from a list of 23 "learner groups" focused in the Biomedical and Socio-Behavioral disciplines.

When an individual registers in the appropriate "learner group," the site automatically opens the training modules to be completed. There are online tests at the end of most modules.

The Navy-unique module for senior Navy leadership and commanding officers is ready for use. Still in development are modules for Navy-unique training for principal investigators and Institutional Review Board members. Those are expected to be available in the next couple of months.

Marianne Elliott, a DON HRPP staffer who has played a key role in the training development, says Navy personnel will find in the CITI package a distinct civilian orientation. She stresses that the training provides the foundation for human research protections required by all federal agencies.

The CITI-developed modules, she says, are based on the Department of Health and Human Services regulations for the protection of human subjects and the Food and Drug Administration regulations for research with investigational test articles such as drugs, devices, and biologics.

The CITI courses also recognize that the DoD and 16 other federal departments and agencies supporting research with human subjects follow the requirements of the Federal Policy for the Protection of Human Subjects, known as the "Common Rule."

Of critical importance, the CITI modules provide not only the foundation for human research protections, but also the unique additional training required for Navy-sponsored research.

The wait for training is almost over. Information on the CITI-based HRPP training modules will be published soon.

***Also in this Issue:***

***Education Policy***

# DON HRPP Releases New Education Policy

The DON HRPP has unveiled a comprehensive new policy that spells out training requirements for human research protection professionals at Navy commands and DON-supported extramural institutions.

The policy, DON HRPP officials say, is intended to meet Navy requirements for training in research ethics and the responsible conduct of research.

> ***The new policy aims at raising awareness of and improving compliance with human research protections.***

The new policy stipulates that "all personnel who conduct, review, approve, support, manage, or oversee research" must go through initial training and three to six hours of continuing training, depending on their roles and level of responsibilities for human subject research.

Development of the new education policy, officials say, responds to a recent Defense Department initiative to "raise awareness of and compliance with human research protections."

The new DON HRPP policy for human research protection education describes in detail the scope of initial and continuing training based on the roles and responsibilities of personnel. Individuals who serve in multiple roles must meet the most comprehensive training requirement. For continuing training, many options are available that provide the training required in research ethics, human subject protections, and responsible conduct of research.

The training requirements in human research protections are one of nine "core areas" identified by the Public Health Service for responsible conduct of research: data acquisition, management, sharing and ownership; mentor/trainee responsibilities; publication practices and responsible authorship; peer review; collaborative science; human subjects; research involving animals; research misconduct; and conflict of interest and commitment.

The DON HRPP is working with the Collaborative Institutional Training Initiative (CITI) to provide web-based training that meets Navy requirements (page 1).

To ensure their staffers receive the required training, institutions that conduct research may use their own training programs, CITI-based training, or other training programs that meet DON HRPP requirements.

Not all available training programs may fit the bill. In 2000, the National Institutes of Health established a training requirement for investigators and other key human research protections personnel and set up a program to train personnel working on NIH-sponsored research. DON officials point out that the NIH training program, "Human Participant Protections Education for Research Teams" does not meet DON HRPP requirements. The NIH program is specifically tailored to NIH policies and procedures and has a biomedical focus.

To meet the minimum requirements, according to the education policy, training programs must: (a) include both initial and continuing training; (b) provide training appropriate to staffers' duties and responsibilities; (c) document clearly the content, learning objectives, speaker qualifications, and other program elements; (d) evaluate the effectiveness of the program in meeting training objectives; (e) provide opportunities for trainees to evaluate program content; and (f) provide for evaluation and refinement of the program.

The DON HRPP policy stipulates individuals must maintain accurate training records, and requires principal investigators (PIs) and other key research personnel to provide verification of training, including copies of training records, when submitting research protocols for review by Institutional Review Boards.

The new policy holds institutions responsible for verifying training and maintaining training documents. Prior to accepting research protocols from PIs, institutions must verify that they have completed their required training. Institutions also must verify that all other personnel working in human research protection have met their training requirements.

***Headquarters-Level Review***

# Headquarters-Level Administrative Review: Getting It Right the First Time

The DON HRPP wants Navy commands to get an A+ when submitting research protocols for headquarters-level administrative review. The goal of review, after all, is to provide constructive feedback to commands to ensure the integrity of the Navy's human research protection program.

DON HRPP staffers say also that feedback from the reviews support the DON HRPP in its efforts to develop integrated, uniform standards for all human subject research throughout the Navy.

In an effort to help commands "get it right the first time," the DON HRPP team looked at a random sample of research protocols and identified several areas in which improvements are needed.

The staff found that many protocols lacked documentation of scientific review, which is required prior to IRB review. In some cases, protocols contained signatures that indicated that a scientific review had been conducted, although the documents required were missing.

Scientific review enables the IRB to carry out its primary role of protecting the safety and welfare of human research subjects. The scientific review assures IRB members that the proposed research uses sound design and methodology. IRBs should receive a written summary of the scientific review. This summary should be included in the package of documents submitted for headquarters-level review.

When submitting a research protocol for headquarters-level review, the relevant section of the IRB meeting minutes pertaining to that protocol must be included. The meeting minutes should identify, for each protocol, whether the research protocol meets the seven criteria required by the federal regulations (32 CFR 219.111). If any criteria are not satisfied, the IRB minutes must document them, report the discussion, and stipulate actions to be taken to satisfy them.

IRBs must document in their minutes any controverted issues and their resolution. For some types of research, IRBs must document specific findings. For example, research with children requires IRBs to address and report the risk category, parental permission, and assent from children, among others.

IRB minutes also must document their recommendations, which can be: approval as submitted; minor modifications required before approval; table for major modification; or disapproval. The minutes must describe the risk level; frequency of continuing review; and the vote.

Commands are responsible for verifying investigators' curriculum vitae (CV) and ensuring that all required training is completed prior to command approval of the research. Commands are responsible for maintaining the source documents (CVs and training certificates) for review during DON HRPP site visits.

Documents that support research protocols, such as Joint Research Review Agreements, excerpts from IRB meeting minutes, and reviews of other committees must be included in the headquarters-level review submission.

The DON HRPP has developed a chart to help eliminate inconsistencies in documents submitted for headquarters-level review. The chart shows which documents must be submitted and which are to be retained by investigators and IRBs/Commands.

This chart is on the forms list at http://navymedicine.med.navy.mil/humanresearch/.

Please share any comments you might have regarding the headquarters-level review by e-mailing us at humanresearch@us.med.navy.mil.

**RESEARCH PROTECTIONS UPDATE** *is published monthly by the Department of the Navy Human Research Protection Program. email address: humanresearch@us.med.navy.mil. Captain Eileen Villasante, publisher, Edward J. Walsh, editor. Telephone: (703) 588-1010; E-mail: walshe@onr.navy.mil.* 

***Animal Protections***

# The Annual BUMED Veterinary Affairs Oversight Visit

***By Col. Mark Gold***

Is it a compliance visit, an assistance visit, or an overly intrusive challenge to a lab's sovereignty? I have heard this question raised several times. Folks want to know what to expect when BUMED visits their facilities to review animal care and use.

SECNAVINST 3900.38C (AR 40-33) requires that each of the Service components ensure compliance with stated animal care and use requirements. The BUMED annual site visit fulfills this requirement.

The DoD has set a policy on the moral high ground for animal care and use. Component-level oversight is part of how that policy is carried out. We cannot overlook this requirement by citing local authority.

> ***We're looking for what I call the ABCs (Appropriate, Beneficial, and Caring) for providing and overseeing animal use.***

Every site visitor has his/her own style. I use the site visits to help share "best practices" from the many other facilities to make programs better. The visited facility, the Navy, and the animals benefit from recommendations for improvements in a program rather than simply documenting the few rare deficiencies without making things better.

What are the standards for review? Navy facilities must abide by provisions of "The Guide for the Care and Use of Laboratory Animals." We conduct a site visit like peeling an onion, peeling back layer upon layer of documents until we get a full view of how the local IACUC (Institutional Animal Care and Use Committee) and veterinary programs review, approve, provide, and monitor animal care and use. We follow all leads, attempting to trace things from the Institutional Official's assignment of IACUC members, through the documentation of IACUC actions, to the authorized ordering of animals and on to the final disposition of all animals on a study.

We are looking for what I call the ABCs (Appropriate, Beneficial, and Caring) for providing and overseeing animal use.

Our team is comprised of experienced laboratory animal veterinary personnel who can bring a large knowledge base and objective view to each visited facility. We encourage discussion, and will make every effort to understand issues when evaluating situations and making recommendations.

It's difficult for us to imagine that no one sees our visit as an "inspection." We cannot avoid completing a formal report, but we try to ensure that the institutional officials know what will be in the report before we leave their facility. How much stress each report generates is based on the individual relationships in the chain of command, and how resources are provided throughout the year. We hope that the responsible parties use the report as a guide to providing resources to animal care and use; either continuing on a commendable route, or adjusting to make things better.

Our office contacts each proposed facility more than a month before the proposed visit to arrange a visit schedule. We can accommodate most special needs. Above all, we want to ensure all facilities that we can serve as a reference and resource to help you fulfill your requirements for providing the best possible animal care and use all year long.

*Col. Mark Gold, USA, is Director of Veterinary Affairs in the Office of Research Protections at the Bureau of Medicine and Surgery.*

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## We're having an Open House!

Plan to visit us at the DON HRPP office, Building 5, BUMED, Washington, DC, 15 November, 9:30 AM – 2:30 PM

Additional information is on the DON HRPP web site at navymedicine.med.navy.mil/HumanResearch/ or e-mail us at HumanResearch@us.med.navy.mil

***New DON HRPP Staff Member at ONR***

# Ivana Sustersic Joins DON HRPP

Ivana Sustersic, a lawyer with extensive experience working with the Navy, joined the DON HRPP in late July to serve as counsel to the program. She'll be based at the Office of Naval Research (ONR) in Arlington, Va. Sustersic worked at ONR earlier in her career, supporting animal and human research protection efforts then underway in the Human Systems Department (now the Warfighter Performance Department) and comments on her return that: "The new HRPP initiative offers a challenge, since the initiative is now more focused and mature than the rudimentary program of a few years ago."

*Ivana Sustersic*

Sustersic, a native of Willowick, Ohio, comes to the DON HRPP team from the Navy's International Programs Office (IPO), where she negotiated Memoranda of Understanding that govern cooperative efforts among the U.S. and its international partners.

She graduated from Kenyon College with an honors degree in economics, and then earned her law degree from Ohio State University's College of Law. While still in law school she, accepted an advance commitment offer from the Navy and, upon graduation, joined the Naval Air Systems Command (NAVAIR), then still based in Arlington.

At NAVAIR, she served as a program attorney on many aircraft and aviation systems acquisition programs, including the SH-60 helicopter and the V-22 Osprey tiltrotor aircraft. She also worked on efforts for the Air Crew Systems program, the E-6A, and the Undergraduate Naval Flight Officer (UNFO) program, among others. Special assignments included details to the Navy Litigation Office T-45 Armed Services Board of Contract Appeals (ASBCA) Litigation Team and to the Assistant General Counsel (Ethics). She remained at NAVAIR through the command's move to Patuxent River, Md., and then accepted a position with ONR. In addition to her work for the Human Systems Department, during her earlier ONR assignment Sustersic also worked extensively on analyses of the environmental impacts and other issues associated with the conduct of littoral warfare development and other oceanographic programs.

Subsequently, Sustersic moved to the Office of Assistant General Counsel (OAGC) for Research, Development, and Acquisition, where she supported the Deputy Assistant Secretary of the Navy (DASN) for Theater Combat Systems and the DASN for Acquisition and Management. She also served as the Navy's legal representative to the Defense Acquisition Regulation (DAR) Council and participated on the Defense Federal Acquisition Regulations Supplement (DFARS) Transformation Task Force. In this position at OAGC RD&A, Sustersic reviewed and coordinated on Secretariat-level approval of certain clinical research efforts.

At Navy IPO, Sustersic played a key role in negotiating and drafting sustainment and follow-on development text for the Joint Strike Fighter (JSF) Production, Sustainment, and Follow-on Development (PSFD) MOU (currently in national staffing). The JSF is in development for the Navy, Marine Corps, and Air Force and for the navies and air forces of eight other nations. She also worked on foreign military sales, ship transfers, and lease agreements.

***New FWA Addendum***

# DON HRPP Introduces Addendum to FWA

The DON HRPP has developed a new document, referred to as an Addendum to a Federalwide Assurance (FWA), that addresses Department of Defense (DoD) and Navy-unique requirements for conducting human subject research.

Civilian institutions the Navy collaborates with, or supports, to conduct human subject research must hold an Assurance for the protection of human subjects. The DON HRPP determined that the Addendum is needed because the FWA does not address the additional Navy requirements.

All human subject research supported by the Department of the Navy (DON) must meet the requirements of the Common Rule (45 CFR 46, Subpart A), the DoD regulations codified at 32 CFR 219, DoD directives, and DON policies (Instructions). Those requirements include medical monitors for research involving more than minimal risk; compliance with additional protections for pregnant women, prisoners, and children outlined in Subparts B, C, and D of 45 CFR 46; and documentation of independent scientific review of research prior to IRB review. The DON HRPP also is developing policy guidance for record keeping, which may include requirements for retention of records and transfer of records to the Navy at the completion of research.

To meet DON requirements, institutions that do not hold an Assurance either may apply for a FWA and submit to DON HRPP an Addendum to their FWA, or obtain a DoD Navy Assurance.

The DON HRPP has issued Addendums to support DON-funded research to the Canadian national defense organization, Defence Research & Development Canada, and to George Mason University, Johns Hopkins University, and Sandia National Laboratories.

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## *Human Research Protection Programs: DoD-Unique Perspectives*

**Marriott Wardman Park Hotel**
**2660 Woodley Road, NW**
**Washington, DC 20008**
**November 14, 2006 - 0800-1630**

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|---|---|
| 0800-0815 | **Welcome and Introductions,** Dr. Bob Foster, DDR&E |
| 0815-0915 | **Then and Now – The Evolution of DoD HRPP,** Mr. Jay Winchester |
| 0915-1045 | **HRPP: Where You Stand Depends on Where You Sit** |
| 1105-1205 | **3 C's – Communication, Cooperation, & Collaboration** |
| 1205-1330 | **Lunch with Mr. Young, DDR&E, as speaker** |
| 1330-1500 | **DoD Component Breakout Sessions** |
| 1520-1630 | **Topic Breakout Sessions** |

**On-line registration via the DD&RE website at**
**www.dtic.mil/biosys/org/hu.html**

**No registration fee for the one-day HRPP: DoD-Unique Perspectives session**

***In Association with the 2006 PRIM&R HRPP Conference***
***Washington, DC - November 16-18, 2006***